# 2010 Data Protection Seminar

**TMA Privacy Office**

## Overview of the TRICARE Management Activity Privacy Board

HEALTH AFFAIRS

TRICARE
Management Activity

# Purpose

- Provide an overview of how and why the TRICARE Management Activity (TMA) Privacy Board was established, how it differs from an Institutional Review Board (IRB)
- Explore insights into the Board's membership, templates, submission process, relationship with the Data Use Agreement (DUA) process, and the types of topics addressed in Board meetings

# Objectives

- Upon completion of this presentation, you should be able to explain the Board's:
  - Approval
  - Establishment
  - Distinction from an IRB
  - Membership
  - Templates
  - Review of submissions
  - Effect on the DUA Process
  - Meetings

Overview of the TMA Privacy Board

# The Board's Approval

- On August 13, 2009, Ms. Embrey, performing the Duties of the Assistant Secretary of Defense (Health Affairs), approved the Action Memo/Memorandum for the Establishment of a TMA Privacy Board and Revision of Section C7.9.1 of Department of Defense Health Information Privacy Regulation (DoD 6025.18-R)
- A Plan of Action and Milestone was developed, the Board's membership was established, templates were created, and the Board received its first submission for review, commencing operations on August 25, 2009

Overview of the TMA Privacy Board

# The Board's Establishment

- The TMA Privacy Board was established for the limited purpose of reviewing research related requests for protected health information (PHI) owned and/or managed by TMA to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and DoD 6025.18-R
- An exception to policy was created so that the TMA Privacy Board could be established pending revision of DoD 6025.18-R to ensure closer alignment to the HIPAA Privacy Rule and to support the Board's creation

Overview of the TMA Privacy Board

# The Board's Distinction from an IRB

- The TMA Privacy Board is **NOT** an IRB and is not authorized to review and/or approve human subjects research regulated under the Federal Policy for the Protection of Human Subjects, known as the Common Rule
- The Common Rule protects individuals who are the subject of research projects against physical harm
  - Informed Consent Requirements
  - IRB reviews and exemption determinations
- The HIPAA Privacy Rule protects against informational harms
  - HIPAA Authorization Requirements
  - Approved Waivers by an IRB and/or Privacy Board

Overview of the TMA Privacy Board

# The Board's Membership

- Leslie Shaffer, TMA Privacy Board Chair
- Rita DeShields, TMA Data Sharing Officer
- Lieutenant Colonel Lorraine Babeu, TMA Exemption Determination Officer
- Dr. Kenneth Cox, retired Col Cox serving as a civilian at the Armed Forces Health Surveillance Center
- Lieutenant Colonel Nancy Fagan, Director of the Military Public Health Clinical and Program Policy, Health Affairs
- Jacob Bournazian, Confidentiality Officer for the Department of Energy, Federal Committee Member on Statistical Methodology

Overview of the TMA Privacy Board

# The Board's Templates

- Research Authorization Review
  - Attaching the template for HIPAA Authorization for use in the project
  - Principal Investigator Certification filing in the TMA Privacy Office
- Application for a Waiver of Authorization
- Required Representations for Reviews Preparatory to Research
- Required Representations for Research on Decedents' Information
- Instructions for Completing TMA Privacy Board Documents

Overview of the TMA Privacy Board

# The Board's Review of Submissions

- The Board conducts "expedited reviews" in accordance with the HIPAA Privacy Rule and DoD 6025.18-R
- A Standard Operating Procedure for the TMA Privacy Board Review Process was developed outlining how submissions to the Board are distributed and reviewed by various Board Members and was implemented on January 1, 2010

# The Board's Review of Submissions (continued)

- The Board also reviews waivers approved by IRBs that conduct HIPAA reviews to ensure that all required elements in the HIPAA Privacy Rule and DoD 6025.18-R are contained in the waiver document and will accept such approvals without a separate Board review

Overview of the TMA Privacy Board

# The Board's Effect on the DUA Process

- Research-related DUAs received in the TMA Privacy Office are promptly reviewed by a Research Data Element Identification Workgroup
  - Distinguish between de-identified versus PHI requests under the HIPAA Privacy Rule and DoD 6025.18-R standards
  - Flag and act on requests for potential "limited data sets" (LDS) that do not need Board Approval but will require signature on a separate LDS agreement to ensure HIPAA assurances are met
  - Confirm research DUAs that require access to PHI and send DUA name/project to the TMA Privacy Board for further action

Overview of the TMA Privacy Board

# The Board's Effect on the DUA Process (continued)

- DUAs are used to monitor and ensure all required research-related approvals are in place
  - IRB approval, where applicable
  - Approval from the TMA Health Program Analysis and Evaluation Division, where applicable
  - TMA Privacy Board, where applicable

Overview of the TMA Privacy Board

# The Board's Effect on the DUA Process (continued)

- Research-related DUAs will not be approved authorizing access to Military Health System data owned and/or managed by TMA until any and all approvals are received
  - The order in which various approvals are received may vary
  - The DUA process verifies compliance with applicable federal privacy and HIPAA security laws and regulations

Overview of the TMA Privacy Board

# Board Meetings

- The Board agreed to meet monthly and/or on an “as needed” basis during its infancy, with a plan to meet at a minimum on a quarterly basis
- Board meetings are scheduled by the Chair
- Board meetings review the status of submissions, recommended revisions to templates, the creation/revisions of templates, standards for consistent reviews, issues and/or questions about reviews, and any other information pertinent to the Board and/or its mission

# Summary

- You should now be able to explain the Board's:
  - Approval
  - Establishment
  - Distinction from an IRB
  - Membership
  - Templates
  - Review of submissions
  - Effect on the DUA Process
  - Meetings

# Resources

- DoD 6025.18-R, “DoD Health Information Privacy Regulation”, January 2003
- DoD 8580.02-R, “DoD Health Information Security Regulation”, July 2007
- To subscribe to the TMA Privacy Office E-News, go to: http://www.tricare.mil/tma/privacy/mailinglist.aspx
- E-mail Privacymail@tma.osd.mil for subject matter questions
- E-mail tmaprivacyboard@tma.osd.mil for questions concerning the TMA Privacy Board

# Appendix

- PHI: Individually identifiable health information that is transmitted or maintained by electronic or any other form or medium, except as otherwise contained in employment records held by a covered entity in its role as an employer
- LDS: PHI that excludes the 16 direct identifiers of the individual or of relatives, employers, or household members of the individual

Source: DoD 6025.18-R, "DoD Health Information Privacy Regulation", January 23, 2004